



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HF-I-35 (pre 4/2/00)  
Public Health Service  
m4189m

Food and Drug Administration  
New Orleans District Office  
6600 Plaza Drive, Suite 400  
New Orleans, LA 70127

September 5, 2000

Barry  
9/11/00  
JEP

**CERTIFIED MAIL - RETURN RECEIPT REQUESTED**

**FACILITY ID# 216408**

Rosmond M. Tyler, Administrator  
Bolivar General Hospital  
650 Nuckolls Road  
P.O. Box 509  
Bolivar, TN 38008

**Warning Letter No. 00-NSV-23**

Dear Mr. Tyler:

Your facility was inspected on August 30, 2000 by a representative of the State of Tennessee on contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

**Level 1**

Phantom QC records were missing for 7 weeks for unit-1, [REDACTED] ([REDACTED]), OTH, Room: Mammo

This specific deficiency appeared on the Post Inspection Report, which was mailed out to your facility by the State inspector, along with instructions on how to respond to this finding. This deficiency may be symptomatic of serious problems that could compromise the quality of mammography at your facility and potentially overexpose both patients and employees involved with mammography.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of this deficiency as identified and to promptly initiate permanent corrective action.

If you fail to properly address this deficiency, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.


- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations.

If your facility is unable to complete the corrective actions within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125. Any questions in regard to this letter or how to ensure you are meeting MQSA standards, please call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,

  
Carl E. Draper  
Director, New Orleans District

CED:KRS:man

cc: State of Tennessee  
Dept. Of Environment and Conservation  
2700 Middlebrook Pike, Suite 220  
Knoxville, TN 37921  
ATTN: Darlene Nalepa-Whitmill

Priscilla F. Butler, M.S.  
Director, Breast Imaging Accreditation Programs  
Standards and Accreditation Department  
American College of Radiology  
1891 Preston White Drive  
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